Serial No.: 10/017,905 - 2 - Art Unit: 1644

Conf. No.: 7653

In the Claims

Applicant has submitted a new complete claim set showing marked up claims with insertions indicated by underlining and deletions indicated by double bracketing. This listing of claims will replace all prior versions and listings of claims in the application.

Please amend claims 1, 6, 11, 16, 21, 55, and 57 as noted below. Please add new claims 68-76.

1. (Currently amended) A method for characterizing an apparently healthy individual's risk profile of developing future diabetes or <u>one or more</u> diabetic complications, comprising:

obtaining a level of C-reactive protein in <u>a blood sample from</u> the individual, and if said level of C-reactive protein is about 0.30 mg/dl [[of blood]] or higher <u>in the blood sample from the individual</u>, then <u>characterizing</u> said individual [[has]] <u>as having</u> an increased risk of developing future diabetes or <u>one or more</u> diabetic complications, <u>wherein the diabetic complications are diabetic ketoacidosis</u>, <u>hyperosmolar coma</u>, <u>retinopathy</u>, <u>diabetic nephropathy</u>, <u>diabetic neuropathy</u>, <u>or diabetic foot ulcers</u>.

- 2-5. (Canceled)
- 6. (Currently amended) The method of claim 1, wherein the level of C-reactive protein is about 0.60 mg/dL [[of blood]] or higher in the blood sample from the individual.
- 7-10. (Canceled)
- 11. (Currently amended) A method for characterizing an individual's risk profile of developing future diabetes or <u>one or more</u> diabetic complications, comprising:

Serial No.: 10/017,905 - 3 - Art Unit: 1644

Conf. No.: 7653

obtaining a level of C-reactive protein <u>in a blood sample from</u> the individual, wherein a level of C-reactive protein about 0.30 mg/dl [[of blood]] or higher <u>in the blood sample from the individual</u> establishes a first risk value,

obtaining a level of a glycosylated hemoglobin in <u>a blood sample from</u> the individual, comparing the level of the glycosylated hemoglobin to a second predetermined value specific for the diagnosis of diabetes or <u>one or more</u> diabetic complications to establish a second risk value, and

characterizing the individual's risk profile of developing diabetes or <u>one or more</u> diabetic complications based upon the combination of the first risk value and the second risk value, wherein the combination of the first risk value and second risk value establishes a third risk value different from said first and second risk values.

12-15. (Canceled)

16. (Currently amended) The method of claim 11, wherein the level of C-reactive protein is about 0.60 mg/dL [[of blood]] or higher in the blood sample of the individual.

17-20. (Canceled)

21. (Currently amended) A method for evaluating the likelihood that an individual will benefit from treatment with an agent for reducing the risk of diabetes or [[reducing the risk of]] one or more diabetic complications, wherein the agent [[selected from the group consisting of]] is insulin, a hypoglycemic agent, an anti-inflammatory agent, a lipid lowering agent, a calcium channel blocker, a beta-adrenergic receptor blocker, a cyclooxygenase-2 inhibitor, [[and]] or an angiotensin system inhibitor, comprising:

obtaining a level of C-reactive protein in a blood sample from the individual, and

Serial No.: 10/017,905 - 4 - Art Unit: 1644

Conf. No.: 7653

if said level of C-reactive protein is about 0.30 mg/dl [[of blood]] or higher in the blood sample from the individual, then characterizing said individual [[will]] as likely to benefit from treatment with said agents, wherein the diabetic complications are diabetic ketoacidosis, hyperosmolar coma, retinopathy, diabetic nephropathy, diabetic neuropathy, or diabetic foot ulcers.

- 22-51. (Canceled)
- 52. (Previously presented) The method of claim 21, wherein the agent is a hypoglycemic agent.
- 53-54. (Canceled)
- 55. (Currently amended) The method of claim 21, wherein the level of C-reactive protein is about 0.60 mg/dL [[of blood]] or higher in the blood sample from the individual.
- 56. (Canceled)
- 57. (Currently amended) The method of claim 21, wherein the agent is [[an]] insulin.
- 58-61. (Canceled)
- 62. (Previously presented) The method of claim 21, wherein the agent is an antiinflammatory agent.
- 63. (Previously presented) The method of claim 21, wherein the agent is a lipid lowering agent.

Serial No.: 10/017,905 - 5 - Art Unit: 1644

Conf. No.: 7653

64. (Previously presented) The method of claim 21, wherein the agent is a calcium channel blocker.

- 65. (Previously presented) The method of claim 21, wherein the agent is a beta-adrenergic receptor blocker.
- 66. (Previously presented) The method of claim 21, wherein the agent is a cyclooxygenase-2 inhibitor.
- 67. (Previously presented) The method of claim 21, wherein the agent is an angiotensin system inhibitor.
- 68. (New) A method for evaluating the likelihood that an individual will benefit from treatment with an agent for reducing the risk of one or more diabetic complications, wherein the agent is insulin or a hypoglycemic agent, comprising:

obtaining a level of C-reactive protein in a blood sample from the individual, and if said level of C-reactive protein is about 0.30 mg/dl or higher in the blood sample from the individual, then characterizing said individual as likely to benefit from treatment with said agent.

69. (New) A method for characterizing an apparently healthy individual's risk profile of developing one or more diabetic complications, comprising:

obtaining a level of C-reactive protein in a blood sample form the individual, and if said level of C-reactive protein is between about 0.30 mg/dl and about 0.6 mg/dl in the blood sample from the individual, then characterizing said individual as having an increased risk of developing one or more diabetic complications.

Serial No.: 10/017,905 - 6 - Art Unit: 1644

Conf. No.: 7653

70. (New) A method for evaluating the likelihood that an individual will benefit from treatment with an agent for reducing the risk of one or more diabetic complications, wherein the agent is insulin, a hypoglycemic agent, an anti-inflammatory agent, a lipid lowering agent, a calcium channel blocker, a beta-adrenergic receptor blocker, a cyclooxygenase-2 inhibitor, or an angiotensin system inhibitor, comprising:

obtaining a level of C-reactive protein in a blood sample from the individual, and if said level of C-reactive protein is between about 0.30 mg/dl and about 0.6 mg/dl in the blood sample from the individual, then characterizing said individual as likely to benefit from treatment with said agent.

- 71. (New) The method of claim 1, wherein the diabetes or one or more diabetic complications is diabetes.
- 72. (New) The method of claim 1, wherein the diabetes or one or more diabetic complications is one or more diabetic complications.
- 73. (New) The method of claim 11, wherein the diabetes or one or more diabetic complications is diabetes.
- 74. (New) The method of claim 11, wherein the diabetes or one or more diabetic complications is one or more diabetic complications.
- 75. (New) The method of claim 21, wherein the agent is an agent for reducing the risk of diabetes.
- 76. (New) The method of claim 21, wherein the agent is an agent for reducing the risk of one or more diabetic complications.